OCT 2 2 2001

## SECTION F: 510(k) Summary

K 013173

**510(k) SUMMARY**

This summary of safety and effectiveness information is submitted in compliance with 21CFR807.92.

1. **Application Date:**
   September 11, 2001

2. **Applicant Information:**
   Polymer Technology Systems, Inc.
   7736 Zionsville Road
   Indianapolis, IN 46268
   **Contact Person**: Margo Enright
   **Phone Number**: 317-870-5610
   **FAX Number**: 317-870-5608
   **e-mail:** mme@diabetes-testing.com

3. **Trade Names:**
   BioScanner Plus
   Lipid Panel Test Strips

4. **Description:**
   The BioScanner Plus is a reflectance photometer for *in vitro* diagnostic use with Polymer Technology System's (PTS) test strips to measure color developed in a chemical reaction that occurs when whole blood is placed on a test strip. The color is measured and converted into concentration for each analyte.
   The Lipid Panel Test Strips are dry phase test strips that are constructed from a plastic strip holder that holds chemically treated membranes. When whole blood is placed on the test strip, the membranes first separate and isolate the red blood cells, allowing the serum/plasma to flow to the reaction membrane and react to produce a color change. The Lipid Panel Test Strips are for *in vitro* diagnostic use with the BioScanner Plus reflectance photometer.

   The only modification that was made to the BioScanner to produce the BioScanner Plus was: A fourth optical read window was added to the three optical read windows in the BioScanner.

   The only modification that was made to the Cholesterol, HDL Cholesterol and Triglycerides test strips to produce the Lipid Panel Test Strips is that the reaction membranes from the three individual test strips were assembled together on one test strip holder that holds all three at once.

5. **Classification Names:**
   Cholesterol test system
   Lipoprotein test system
   Panel: Clinical Chemistry 75

6. **Facility Address:**
   7736 Zionsville Road
   Indianapolis, IN 46268

7. **Device Classification:**
   Class I (Regulation: 21 CFR 862.1475, 862.1175, 862.1705)

8. **Intended Use:**

The Lipid Panel Test Strips are intended to measure cholesterol, HDL cholesterol and triglycerides in whole blood on a BioScanner Plus analyzer. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

9. **Reason for 510(k):**

Device Modification

10. **Predicate Device Information**

The following are the predicate devices for determination of substantial equivalence:

**Name:** BioScanner, BioScanner Cholesterol, HDL Cholesterol and Triglycerides Test Strips from Polymer Technology Systems

**Device Company:** Polymer Technology Systems, Inc.
**510(k) Numbers:** K972669, K981493, K990247, and K991894

**Similarities and Differences between BioScanner Plus and the Predicate Device**

Similarities

- Both systems determine Total Cholesterol, HDL Cholesterol, and Triglycerides concentrations in whole blood.
- Both systems use the same method of red blood cell separation.
- Both systems use the same reaction membranes for blood separation and color development.
- Both systems use a reflectance photometer to convert the intensity of color produced in a colorimetric chemical reaction into total cholesterol, HDL cholesterol, and Triglycerides results.
- Both systems contain a lot specific electronically erasable programmable read-only memory (EEPROM) chip in the same package with the strips. The EEPROM chip has the curve information programmed into it based on a multipoint curve that is established for each lot. The user inserts this chip into the meter with each new lot of test strips.
- Both systems contain, on the EEPROM, the failsafe feature ensuring that the test strip lot and calculation EEPROM match. If the EEPROM and strip lot number do not match, an error message is displayed.

Differences

1. The BioScanner Test System (K972669) has three optical windows

   The BioScanner Plus has four optical windows.

2. The BioScanner Test System Cholesterol (K981493), HDL Cholesterol (K990247) and Triglycerides (K991894) Test Strips are constructed on three separate strips.
   The Lipid Panel Test Strips combine the cholesterol, HDL cholesterol and triglycerides into one test strip.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 22 2001

Mr. James M. Connolly, CEO
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Re: k013173
Trade/Device Name: BioScanner Plus and Lipid Panel Test Strips
Regulation Number: 21 CFR 862.1175, 21 CFR 862.1475, 21 CFR 862.1705
Regulation Name: Cholesterol (total) test system, Lipoprotein test system, Triglyceride test system
Regulatory Class: Class I, reserved, Class I, reserved, Class I, reserved
Product Code: CHH, LBR, JGY
Dated: September 11, 2001
Received: September 24, 2001

Dear Mr. Connolly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K013173

DEVICE NAME: BioScanner Plus and Lipid Panel Test Strips

INDICATIONS FOR USE:

The Lipid Panel Test Strips are intended to measure cholesterol, HDL cholesterol and triglycerides in whole blood on a BioScanner Plus analyzer. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism , or various endocrine disorders.

The BioScanner Plus is intended to be used by healthcare professionals to measure blood analytes on a test strip.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ____
(Optional Format 1-2-96)

Kevin Alexander for Ivan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013173